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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,627	10/08/2003	Carl H. June	WYS-01402	7408

25181 7590 06/27/2006

FOLEY HOAG, LLP
PATENT GROUP, WORLD TRADE CENTER WEST
155 SEAPORT BLVD
BOSTON, MA 02110

EXAMINER	
WEHBE, ANNE MARIE SABRINA	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,627	JUNE, CARL H.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 8-9, and 15-22 , drawn to methods for inhibiting a T cell response comprising contacting a T cell with an inhibitor of phosphatidylinositol 3-kinase and a second agent which is an inhibitor of a protein tyrosine kinase, and methods for inducing unresponsiveness to an antigen in a T cell comprising contacting the T cell with an antigen and an inhibitor of phosphatidylinositol 3-kinase, classified in class 514, subclass 1.

II. Claims 1-6, 10-12, and 15-22, drawn to methods for inhibiting a T cell response comprising contacting a T cell with an inhibitor of phosphatidylinositol 3-kinase and a second agent which is a tyrosine phosphatase or activator of a tyrosine phosphatase, and methods for inducing unresponsiveness to an antigen in a T cell comprising contacting the T cell with an antigen and an inhibitor of phosphatidylinositol 3-kinase, classified in class 514, subclass 1.

III. Claims 1-6, and 13-22, drawn to methods for inhibiting a T cell response comprising contacting a T cell with an inhibitor of phosphatidylinositol 3-kinase and a second agent which is a molecule that binds to an activates CD45, and methods for inducing unresponsiveness to an antigen in a T cell comprising contacting the T cell with an antigen and an inhibitor of phosphatidylinositol 3-kinase, classified in class 514, subclass 1.

IV. Claims 23-27, 29, and 32-38, drawn to methods for stimulating a T cell response by contacting the T cell with an agent which stimulates production of D-3 phosphoinositides in the T cell and a second agent which is an activator of a protein tyrosine kinase, classified in class 514, subclass 1.

V. Claims 23-27, and 30-38, , drawn to methods for stimulating a T cell response by contacting the T cell with an agent which stimulates production of D-3 phosphoinositides in the T cell and a second agent which is an inhibitor of a cellular tyrosine phosphatase, classified in class 514, subclass 1.

VI. Claims 39-43, drawn to methods of identifying an inhibitor of a phosphatidylinositol 3-kinase, classified in class 435, subclass 4.

VII. Claims 44-45, drawn to methods of identifying an activator of phosphatidylinositol 3-kinase, classified in class 435, subclass 4.

Claim 7 link(s) inventions I-III, and claim 28 links inventions IV-V. The restriction requirements among the linked inventions is subject to the nonallowance of the linking claim(s), claim 7 or claim 28. Upon the indication of allowability of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise requiring all the limitations of the allowable linking claim(s) will be rejoined and fully examined for patentability in accordance with 37 CFR 1.104 Claims that require all the limitations of an allowable linking claim will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after

final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Applicant(s) are advised that if any claim(s) including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. In re Ziegler, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, while the methods share the step of contacting a T cell with an inhibitor of phosphatidylinositol 3-kinase, the methods are patentably distinct in that they each further involve contacting the cell with second agents- an inhibitor of a protein tyrosine kinase, or a tyrosine phosphatase, or a molecule that binds to and activates CD45- that are materially different in structural, chemical, physical, and functional properties. Based on the properties of the second agent, inventions I-III do not overlap in scope and are not obvious variants. Further, the combination of the inhibitor and second agent in each invention results in materially different modes or operation and function. Therefore, for the reasons set forth, the

search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine all of inventions I-III together.

Inventions IV-V are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, while the methods share the step of contacting a T cell with an agent which stimulates production of D-3 phosphoinositides in the T cell, the methods are patentably distinct in that they each further involve contacting the cell with second agents- an activator of a protein tyrosine kinase, or an inhibitor of a tyrosine phosphatase - that are materially different in structural, chemical, physical, and functional properties. Based on the properties of the second agent, inventions IV-V do not overlap in scope and are not obvious variants. Further, the combination of the first agent and second agent in each invention results in materially different modes or operation and function. Therefore, for the reasons set forth, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine all of inventions IV-V together.

Inventions I-III and IV-V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to methods for achieving opposite effects on a T cell and utilize agents which are completely unrelated in structure and function. The agents used in the methods of inventions I-III are not capable of use in the methods of IV-V and vice versa. Further, the modes

of operation and effects of the agents for each set of inventions is opposite. As such, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine all of inventions I-V together.

Inventions I-V and inventions VI-VII are patentably distinct in the methods of inventions VI-VII are drawn to identifying inhibitors or activators of phosphatidylinositol 3-kinase. These methods involve methods steps and techniques that are not required for and not capable of use with the methods of inventions I-V. Further, the methods of inventions I-V includes methods steps and second agents which are not required or capable of use with the screening methods of inventions VI-VII. As such, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine all of inventions I-VII together.

Finally, inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to methods for identifying an agents which have opposite effects on a T cell. Thus, the agents to be tested in each method are completely unrelated in structure and function. The agents used in the methods of inventions VI are not capable of use in the methods of VII and vice versa. Further, the modes of operation and effects of the agents for each set of inventions is opposite. As such, the search for each invention is not co-extensive and it would place an undue burden on the examiner to search and examine all of inventions VI-VII together.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter,

different search requirements, and different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of antigens for inventions I-III:

a) alloantigens

b) autoantigens

c) xenoantigens.

The species are independent or distinct because each of a)-c) represents a distinct class of antigens which are derived from different sources are associated with substantially different diseases/disorders, and have different properties in a host such that the search an examination required for each class of antigens is not co-extensive and would place an undue burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 15-17, and 20 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an

allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

This application contains claims directed to the following patentably distinct species of antigens for inventions IV-V:

a) tumor antigens

b) bacterial antigens

c) viral antigens

d) fungal antigens

e) parasite antigens.

The species are independent or distinct because each of a)-c) represents a distinct class of antigens which are derived from different sources, are associated with substantially different diseases/disorders, and have different properties in a host such that the search an examination required for each class of antigens is not co-extensive and would place an undue burden on the examiner.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 32-33 and 36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species **and** invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Dave Nguyen, can be reached at (571) 272-0731. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER